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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,712	11/08/2005	Marc Eloit	270423US0XPCT	9314

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EXAMINER	
MAKAR, KIMBERLY A	
ART UNIT	PAPER NUMBER
1636	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	03/01/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 03/01/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/530,712	ELOIT ET AL.	
	Examiner	Art Unit	
	Kimberly A. Makar	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 16-19* is/are rejected.

7)☒ Claim(s) *7-15,20 and 21* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 April 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *07/06/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Oath/Declaration

1. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
It was not executed in accordance with either 37 CFR 1.69.

The oath is executed in English, except for the section containing applicant signatures, addresses and citizenship. Because the main body of the oath is filled out in English, it is assumed that applicants comprehend English. As such, the execution of the section of the Oath containing signatures, addresses and citizenship should also be in English.

37 CFR 1.69 requires that oaths and declarations be in a language which is understood by the individual making the oath or declaration, i.e., a language which the individual comprehends. If the individual comprehends the English language, he or she should preferably use it. If the individual cannot comprehend the English language, any oath or declaration must be in a language which the individual can comprehend. If an individual uses a language other than English for an oath or declaration, the oath or declaration must include a statement that the individual understands the content of any documents to which the oath or declaration relates. If the documents are in a language the individual cannot comprehend, the documents may be explained to him or her so that he or she is able to understand them.

If applicant does not understand English, a new oath in French should be submitted along with the accompanying translation and statement.

Claim Objections

2. Claims 7-15 and 20-21 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend on another multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims 7-15 and 20-21 have not been further treated on the merits.

Abstract

3. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

4. The abstract of the disclosure is objected to because it contains the legal phraseology "said". Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 (and dependent claims 2-6) recite a

recombinant adenovirus comprising the limitation Genbank accession number J04368. The sequence of J04368 is not listed in the sequence listing, nor in the specification. The sequence is essential subject matter of the invention, as such, the sequence of J04368, *as published at the time the invention was made*, must be added to the specification, along with a new sequence listing in order to comply with the written description requirement.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claim 1 recites the phrase "the genome of type 2 canine adenovirus (Genbank J04368)" which is unclear. The Genbank J04368 does not comprise the entire genome for canine type 2 adenovirus, but only the portions corresponding to the ITR, E1A, E1B and IX proteins. Are these portions the only portions that are important for the invention? Can the rest of the recombinant adenovirus thus comprise other portions of other types of adenovirus genomes, such as from human? Or other canine serotypes, such as canine type 5 adenovirus? A skilled artisan would be unable to determine the metes and bounds of the claimed invention.

10. Claim 1 recites the limitation "the original replicating adenovirus" in claim 1. There is insufficient antecedent basis for this limitation in the claim.

11. Claim 2 recites the phrase, "the deleted portion consists of all or part of the region of the genome of the original replicating adenovirus corresponding to that located between positions 311 and 319 in the genome of type 2 canine adenovirus" in claim 1. However, claim 1 recites the presence of two deleted portions of a canine adenovirus genome, one between positions 311 and 499, and a second between positions 311 and 401. Thus, to which deletion portions would this 311 to 319 portion be limited to? A skilled artisan would be unable to determine the metes and bounds of the claimed invention.

12. Claim 16 recites the limitation "the genome of an adenovirus" in step α of claim 16. There is insufficient antecedent basis for this limitation in the claim.

13. Claim 18 recites the limitation "the insertion site" in claim 16. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claims 1, 3-6, and 16-19 are rejected under 35 U.S.C. 102(b) as being taught by Soudais et al (Characterization of cis-Acting Sequences Involved in Canine Adenovirus Packaging. Molecular Therapy, 2001. 3(4):631-640) listed in applicant IDS 1449 form

dated 07/06/05. Claims 1, 3-6, 16-19 recite a recombinant replicating adenovirus comprising a deletion of all or part of the canine adenovirus type 2 genome between positions 311-499 or 311-401 (claim 1) wherein the deleted portion comprises the deletion between base pairs 318-401 (claim 3) and wherein in the deleted portion additionally comprises all or part of the region between 311-319 and/or 400-439 and/or 438-499 (claim 4). The recombinant adenovirus is further limited wherein it additionally comprises a heterologous sequence of interest inserted into its genome (claim 5), and that the heterologous sequence is inserted in the region located between base pairs 311-319 in the genome of type 2 canine adenovirus (claim 6).

16. Soudais et al teaches the generation of recombinant canine type 2 adenoviruses (see abstract). Specifically, she teaches a series of deletion mutants in which the GFP gene is inserted via homologous recombination into the E1A promoter and coding region. Specifically she deletes portions of the genome from base pair 356 to the E2 region at base pair 2145 (see figure 1) by inserting a heterologous GFP cassette and then inserting a loxP sites (2 unique restriction sites) at base pairs 173 and 2081 (figure 1b, and page 635 second column last paragraph –636 first column). Soudais teaches the Cav2 used in the experiments has the Genbank accession number J04368 (page 632, material and methods section.) Soudais teaches the particular vector CAVGFP-4Δ5, which specifically has the base pairs 302-356 deleted from the CAV2 genome, thus the vector comprises the deletion of pairs 311-319, and has the GFP cassette inserted in this region (see figure 2). Soudais teaches the generation of virus using these constructs (figure 5). Thus Soudais teaches the claimed invention.

17. Claims 16-19 are rejected under 35 U.S.C. 102(b) as being taught by Crouzet et al (Recombinatorial Construction in Escherichia coli of Infection Adenoviral Genomes. PNAS, 1997. 94:1414-1419) of record 04/08/2005 listed on page 10 of the instant specification. Claim 16 recites a method for preparing a recombinant adenovirus by homologous recombination in a prokaryotic cells comprising a) introducing into the prokaryotic cell (1) a plasmid comprising the genome of an adenovirus and a first selection gene and (2) a previously linearized DNA fragment which comprises a heterologous sequence flanked by sequences which are homologous to those flanking the site of said plasmid wherein the insertion is to be effected and which includes a second selection gene which is different from the first and b) culturing the prokaryotic cell under selective conditions in order to make it possible to generate and select cells which harbor recombinant plasmids which are expressing the first and second genes and c) isolating the genome of the recombinant adenovirus from selected prokaryotic cells. The method is further limited wherein the plasmid is in circular form (claim 17) and the plasmid has been previously linearized by cleavage at a restriction site located outside the insertion site (claim 18) and wherein the second selection gene is flanked by 2 identical or different restriction sites which are absent from the genome of the adenovirus which is included in the plasmid of stop a) (claim 19).

18. Crouzet teaches a two-step gene replacement procedure for generation of infectious adenovirus genomes in E. coli (prokaryotic cells) (see abstract). The procedure requires two different selection genes, one on the adenovirus genome, and the second on the insert (see abstract, and figure 1 with legend). Crouzet teaches that

all of the vectors are linearized at some point for manipulation using a variety of restriction sites at different points of insertion – thus at least one previously linearized outside of an insertion site (see materials and methods section, page 1415). Selection of homologous recombination only occurs in crossover events when the second selection gene is inserted into the vector comprising the rest of the adenoviral genome and the first selection gene (see page 1415, Selection Protocols for Homologous Recombination section, and figure 1). Thus some recombinant vectors require Tetracycline and Ampicillin resistance, or Tetracycline and Kanamycin resistance, among others. Figure 1A shows the generation of pXL2689 in which circularized vector pFG144 is recombined with pXL2672. pXL2672 comprises the regions of homology for the recombination that are flanked with two identical PacI restriction sites that are not found in vector pFG144 (see figure 1a, and page 1416 results section). Thus Crouzet teaches the claimed invention.

Conclusion

19. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly A. Makar, Ph.D. whose telephone number is 571-272-4139. The examiner can normally be reached on 8AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kam/02/13/07

DAVID GUZO
PRIMARY EXAMINER